

Notice of Allowability

Application No.

09/978,343

Applicant(s)

HOSTETTER ET AL.

Examiner

Claire M. Kaufman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the telephone interview of 3/4/04 for the attached Ex's Amendment.
2. ☒ The allowed claim(s) is/are 28-31, 33-47 and 49-66.
3. ☒ The drawings filed on 10/15/01 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

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EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ann M. Muetting on March 4, 2004.

The application has been amended as follows:

Amendments to the Claims

This listing of claims replaces all prior versions and listings of claims:

- ¹
~~28.~~ [previously presented] An isolated and purified antibody to a *Candida albicans* integrin-like protein, wherein the protein has an amino acid sequence having SEQ ID NO:2, and wherein the antibody blocks *Candida albicans* adhesion to epithelial and/or endothelial cells.
- ²
~~29.~~ [previously presented] The antibody of claim ¹~~28~~ wherein the antibody is monoclonal or polyclonal.
- ³
~~30.~~ [previously presented] The antibody of claim ¹~~28~~ wherein the antibody blocks *Candida albicans* adhesion to epithelial and/or endothelial cells by at least about 30 percent.
- ⁴
~~31.~~ [previously presented] The antibody of claim ¹~~28~~ wherein the antibody blocks *Candida albicans* adhesion to epithelial and/or endothelial cells by at least about 50 percent.
32. [canceled]
- ¹²
~~33.~~ [currently amended] The antibody of claim ¹¹~~49~~ wherein the antibody is monoclonal or polyclonal.

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⁶
~~34~~. [previously presented] An isolated and purified antibody to a polypeptide, wherein the polypeptide has the amino acid sequence of SEQ ID NO:3, and wherein the antibody blocks *Candida albicans* adhesion to epithelial and/or endothelial cells.

⁹
~~35~~. [previously presented] The antibody of claim ⁶~~34~~ wherein the antibody blocks *Candida albicans* adhesion to epithelial and/or endothelial cells by at least about 30 percent.

¹⁶
~~36~~. [previously presented] An isolated and purified antibody to a peptide consisting of an amino acid sequence selected from the group consisting of:

- (a) YLS PTN NNN SKN VSD MDL HLQ NL (SEQ ID NO:4);
- (b) DWK LED SND GDR EDN DDI SRF EK (SEQ ID NO:5);
- (c) SKS ANT VRG DDD GLA SA (SEQ ID NO:6);
- (d) DHL DSF DRS YNH TEQ SI (SEQ ID NO:7); and
- (e) WIQ NLQ EII YRN RFR RQ (SEQ ID NO:8).

¹⁷
~~37~~. [previously presented] The antibody of claim ¹⁶~~36~~ wherein the antibody is monoclonal or polyclonal.

²²
~~38~~. [previously presented] An isolated and purified antibody to a peptide having of an amino acid sequence selected from the group consisting of:

- (a) YLS PTN NNN SKN VSD MDL HLQ NL (SEQ ID NO:4);
- (b) DWK LED SND GDR EDN DDI SRF EK (SEQ ID NO:5);
- (c) SKS ANT VRG DDD GLA SA (SEQ ID NO:6);
- (d) DHL DSF DRS YNH TEQ SI (SEQ ID NO:7); and
- (e) WIQ NLQ EII YRN RFR RQ (SEQ ID NO:8), wherein the antibody blocks *Candida albicans* adhesion to epithelial and/or endothelial cells.

²⁴
~~39~~. [previously presented] The antibody of claim ²²~~38~~ wherein the antibody blocks *Candida albicans* adhesion to epithelial and/or endothelial cells by at least about 30 percent.

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²⁷
~~40~~. [previously presented] An isolated and purified antibody to a polypeptide with integrin-like motifs encoded by a polynucleotide that hybridizes to DNA complementary to DNA having SEQ ID NO:1 under stringency conditions of hybridization in buffer containing 5x SSC, 5x Denhardt's, 0.5% SDS, 1 mg salmon sperm/25 mls of hybridization solution incubated at 65°C overnight, followed by high stringency washing with 0.2x SSC/0.1% SDS at 65°C, wherein the polypeptide with integrin-like motifs contains an I domain, two EF-hand divalent cation binding sites, a sequence sufficient to form a transmembrane domain, an internal RGD tripeptide, and a carboxy-terminal sequence having a single tyrosine residue, and wherein the antibody blocks *Candida albicans* adhesion to epithelial and/or endothelial cells.

²⁸
~~41~~. [previously presented] The antibody of claim ²⁷~~40~~ wherein the polypeptide comprises an amino acid sequence selected from the group consisting of SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, and SEQ ID NO:8.

²⁹
~~42~~. [previously presented] The antibody of claim ²⁷~~40~~ wherein the antibody is monoclonal or polyclonal.

³⁰
~~43~~. [previously presented] The antibody of claim ²⁷~~40~~ wherein the antibody blocks *Candida albicans* adhesion to epithelial and/or endothelial cells by at least about 30 percent.

³¹
~~44~~. [previously presented] The antibody of claim ²⁷~~40~~ wherein the antibody blocks *Candida albicans* adhesion to epithelial and/or endothelial cells by at least about 50 percent.

³³
~~45~~. [previously presented] An isolated and purified antibody to a *Candida albicans* polypeptide encoded by a polynucleotide having SEQ ID NO:1, wherein the antibody blocks *Candida albicans* adhesion to epithelial and/or endothelial cells.

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⁵
~~46.~~ [previously presented] The antibody of claim ¹~~28~~ wherein the antibody blocks adhesion to epithelial and/or endothelial cells by *Candida albicans* selected from a morphological stage of *Candida albicans* development selected from the group consisting of blastospores, germ tubes, and hyphae.

¹⁰
~~47.~~ [previously presented] The antibody of claim ⁶~~34~~ wherein the antibody blocks *Candida albicans* adhesion to epithelial and/or endothelial cells by at least about 50 percent.

48. [canceled]

¹¹
~~49.~~ [currently amended] An isolated and purified antibody to a polypeptide, wherein the polypeptide consists of SEQ ID NO:3, and wherein the antibody blocks *Candida albicans* adhesion to epithelial and/or endothelial cells.

¹³
~~50.~~ [currently amended] The antibody of claim ¹¹~~49~~ wherein the antibody blocks *Candida albicans* adhesion to epithelial and/or endothelial cells by at least about 30 percent.

¹⁴
~~51.~~ [currently amended] The antibody of claim ¹¹~~49~~ wherein the antibody blocks *Candida albicans* adhesion to epithelial and/or endothelial cells by at least about 50 percent.

¹⁸
~~52.~~ [previously presented] The antibody of claim ¹⁶~~36~~ wherein the antibody blocks *Candida albicans* adhesion to epithelial and/or endothelial cells.

¹⁹
~~53.~~ [previously presented] The antibody of claim ¹⁶~~36~~ wherein the antibody blocks *Candida albicans* adhesion to epithelial and/or endothelial cells by at least about 30 percent.

²⁰
~~54.~~ [previously presented] The antibody of claim ¹⁶~~36~~ wherein the antibody blocks *Candida albicans* adhesion to epithelial and/or endothelial cells by at least about 50 percent.

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²⁵
~~55~~. [previously presented] The antibody of claim ²²~~38~~ wherein the antibody blocks *Candida albicans* adhesion to epithelial and/or endothelial cells by at least about 50 percent.

³⁵
~~56~~. [previously presented] The antibody of claim ³³~~48~~ wherein the antibody blocks *Candida albicans* adhesion to epithelial and/or endothelial cells by at least about 30 percent.

³⁶
~~57~~. [previously presented] The antibody of claim ³³~~45~~ wherein the antibody blocks *Candida albicans* adhesion to epithelial and/or endothelial cells by at least about 50 percent.

⁷
~~58~~. [previously presented] The antibody of claim ⁶~~34~~ wherein the antibody is monoclonal or polyclonal.

²³
~~59~~. [previously presented] The antibody of claim ²²~~38~~ wherein the antibody is monoclonal or polyclonal.

³⁴
~~60~~. [previously presented] The antibody of claim ³³~~45~~ wherein the antibody is monoclonal or polyclonal.

¹⁵
~~61~~. [currently amended] The antibody of claim ¹¹~~49~~ wherein the antibody blocks adhesion to epithelial and/or endothelial cells by *Candida albicans* selected from a morphological stage of *Candida albicans* development selected from the group consisting of blastospores, germ tubes, and hyphae.

⁸
~~62~~. [previously presented] The antibody of claim ⁶~~34~~, wherein the antibody blocks adhesion to epithelial and/or endothelial cells by *Candida albicans* selected from a morphological stage of *Candida albicans* development selected from the group consisting of blastospores, germ tubes, and hyphae.

²¹
~~63~~. [previously presented] The antibody of claim ¹⁶~~36~~ wherein the antibody blocks adhesion to epithelial and/or endothelial cells by *Candida albicans* selected from a morphological

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stage of *Candida albicans* development selected from the group consisting of blastospores, germ tubes, and hyphae.

²⁶
64. [previously presented] The antibody of claim ²²38 wherein the antibody blocks adhesion to epithelial and/or endothelial cells by *Candida albicans* selected from a morphological stage of *Candida albicans* development selected from the group consisting of blastospores, germ tubes, and hyphae.

³²
65. [previously presented] The antibody of claim ²⁷40 wherein the antibody blocks adhesion to epithelial and/or endothelial cells by *Candida albicans* selected from a morphological stage of *Candida albicans* development selected from the group consisting of blastospores, germ tubes, and hyphae.

³⁷
66. [previously presented] The antibody of claim ³³45 wherein the antibody blocks adhesion to epithelial and/or endothelial cells by *Candida albicans* selected from a morphological stage of *Candida albicans* development selected from the group consisting of blastospores, germ tubes, and hyphae.

Amendments to the Specification

The specification has been amended by informal Examiner's amendment by addition of U.S. Patent No. 6,346,411.

Please replace the first paragraph (page 1, lines 7-10) with the following:

This application is a divisional of pending U.S. Patent Application Serial No. 09/264,604, filed March 8, 1999, now U.S. No. Patent 6,346,411, which is a divisional of U.S. Patent Application Serial No. 08/642,846, filed May 3, 1996, and issued March 23, 1999 as U.S. Patent No. 5,886,151, both of which are incorporated herein by reference.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance:

The rejection under 35 USC 112, first paragraph, written description is withdrawn in view of Applicants' arguments and upon further consideration. The rejection under 35 USC 102 is withdrawn in view of Applicants' arguments and because of the following teachings of Bendel et al. (previously cited by Applicants, J. Clin. Invest. 92(4):1840, 1993): While it was shown (Figure 2) that OKM1 antibody binds *C. albicans*, it was stated (p. 1843, col. 1, middle of third paragraph) that it "did not inhibit epithelial adhesion of *C. albicans*." If OKM1 was unable to block *C. albicans* adhesion to epithelial cells, the artisan of ordinary skill could not have reasonably expected it to block adhesion to endothelial cells either. Therefore, prior art OKM1 antibody does not meet the limitations set forth in the instant claims.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bujdaková et al. (FEMS Immunol. Med. Microbiol. 18:147, 1997) show the ability of OKM1 antibody to bind *C. albicans* at germ tube and mycelial developmental stages. This reference does not impact that patentability of the claims, but is presented for completeness of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

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fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Inventorship

Applicants' request filed 10/15/01 for deletion of inventors Bendel and Tao, who are not inventors of the invention claimed in the instant application is acknowledged.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (571)272-0873. Dr. Kaufman can generally be reached Monday, Tuesday and Thursday from 8:30AM to 2:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (571)272-0871.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

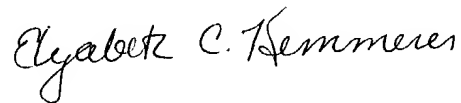
Official papers filed by fax should be directed to (703) 872-9306. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Claire M. Kaufman, Ph.D.



Patent Examiner, Art Unit 1646

March 4, 2004



ELIZABETH KEMMERER
PRIMARY EXAMINER